

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patentees:	Larsen et al.	Confirmation No.:	9323
Serial No.:	10/646,294	Art Unit:	1654
Filing date:	August 22, 2003	Examiner:	R. Teller
Patent No.:	7,585,839	Customer No.:	21559
Issued:	September 8, 2009		
Title:	MEDICAL USES OF INTERCELLULAR COMMUNICATION FACILITATING COMPOUNDS		

REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT

Patentees note that the patent term adjustment set forth in the Determination of Patent Term Adjustment under 35 U.S.C. § 154(b) dated August 19, 2009 in the above-referenced patent appears to be shorter than appropriate.

Patentees submit that the Office has improperly calculated the period for Office delay for failing to apply delays under both 35 U.S.C. §§ 154(b)(1)(A) and 154(b)(1)(B). Patentees further submit that the Office also improperly applied a reduction in patent term adjustment for filing an amendment with the Reply to Notice Allowance, an amendment that was filed upon the Office's request. These matters are explained in detail below.

Office delay

The Patent Office has calculated 1113 days of Office delay in the above patent based on three periods of delay: (1) 518 days under 37 C.F.R. § 1.703(a)(1) for failing to

issue an action under 35 U.S.C. § 132 within 14 months of the filing date (the period running from October 22, 2003 until March 24, 2006); (2) 94 days under 37 C.F.R. § 1.703(a)(2) for failing to issue an action under 35 U.S.C. § 132 within four months of a reply filed under 37 C.F.R. § 1.111 (the period running from July 7, 2008 until October 9, 2008); and (3) 501 days under 37 C.F.R. § 1.703(b) for failing to issue the patent within three years of the filing date (the 1113 day period running from August 22, 2006 until September 8, 2009, less the delays under (1) and (2) listed above, i.e., $1113 - 518 - 94 = 501$).

As explained below, it is improper for the Office to reduce the 1113 delay calculated under 37 C.F.R. § 1.703(b) by the 518 days of delay under 37 C.F.R. § 1.703(a)(1) because these delays do not overlap.

35 U.S.C. § 154(b)(1)(A) states:

Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the Patent and Trademark Office to-

(i) provide at least one of the notifications under section 132 of this title or a notice of allowance under section 151 of this title not later than 14 months after-

the date on which an application was filed under section 111(a) of this title; or

the date on which an international application fulfilled the requirements of section 371 of this title;

(ii) respond to a reply under section 132, or to an appeal taken under section 134, within 4 months after the date on which the reply was filed or the appeal was taken;

* * *

the term of the patent shall be extended 1 day for each day after the end of the period specified in clause (i), (ii), (iii), or (iv), as the case may be, until the action described in such clause is taken.

Corresponding provisions are found in 37 C.F.R. §§ 1.702(a) and 1.703(a). Patentees refer to Office delay under 35 U.S.C. § 154(b)(1)(A), and the corresponding rules, as “A delay.”

35 U.S.C. § 154(b)(1)(B) states:

Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States, not including-

(i) any time consumed by continued examination of the application requested by the applicant under section 132(b);

* * *

the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.

Corresponding provisions are found in 37 C.F.R. §§ 1.702(b) and 1.703(b). Patentees refer to Office delay under 35 U.S.C. § 154(b)(1)(B), and the corresponding rules, as “B delay.”

35 U.S.C. § 154(b)(2)(A) states (emphasis added):

To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any

adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

A corresponding provision is found in 37 C.F.R. § 1.703(f).

The Office has explained its interpretation of the “overlap” provisions of 35 U.S.C. § 154(b)(2)(A) and 37 C.F.R. § 1.703(f) as follows (emphasis added):

[T]he Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), **the entire period during which the application was pending before the Office** (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, **is the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay “overlap” under 35 U.S.C. 154(b)(2)(A).**

Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office

Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283, 34283 (Jun. 21, 2004).

However, the Office’s interpretation was recently rejected by the U.S. District Court for the District of Columbia, which stated (emphasis added in bold; original emphasis in italics):

The operative question under 35 U.S.C. § 154(b)(2)(A) is whether “periods of delay attributable to grounds specified in paragraph (1) overlap.” **The only way that periods of time can “overlap” is if they occur on the same day. If an “A delay” occurs on one calendar day and a “B delay” occurs on another, they do not overlap, and § 154(b)(2)(A) does not limit the extension to one day.** Recognizing this, the PTO defends its interpretation as essentially running the “period of delay” under sub-section (B) from the filing date of the patent application, such that a period of “B delay” *always overlaps* with any periods of “A delay” for the purposes of applying § 154(b)(2)(A).

The problem with the PTO's construction is that it considers the application *delayed* under § 154(b)(1)(B) during the period *before it has been delayed*. That construction cannot be squared with the language of § 154(b)(1)(B), which applies "if the issue of an original patent is *delayed* due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years." (Emphasis added.) "B delay" begins when the PTO has failed to issue a patent within three years, not before.

Wyeth v. Dudas, No. 07-1492 (JR), 2008 U.S. Dist. LEXIS 76063, at *3 (D.D.C. Sep. 30, 2008).

Accordingly, where periods of A delay do not coincide with the period of B delay, the periods of A delay and B delay are not to be considered overlapping under § 154(b)(2)(A), but rather must be added together to determine the overall Office delay.

In the present case, the Office calculated two periods of A delay: The first was a 518 days period beginning on the day after the date that is fourteen months from the application filing date (August 22, 2003) and ending on the date of mailing of an action under 35 U.S.C. § 132 (March 6, 2006). The Office calculated this period as being 518 days, a number which patentees do not dispute.

Because this delay occurred entirely within three years of the application filing date, under the statutory interpretation provided in *Wyeth v. Dudas*, there is no overlap between 518 days of A delay (a period running from October 22, 2004 until March 6, 2006) and the 1113 days of B delay (a period running from August 22, 2006 until September 8, 2009).

Because the second period of A delay, the 94 days for failing to issue an action within four months of a reply (the period running from July 7, 2008 until October 9, 2008), overlaps entirely with the 1113 days of B delay, patentees acknowledge that it is appropriate to subtract this period of time from the B delay.

Patentees therefore submit that the proper delay calculated under 37 C.F.R. §§ 1.702(a) and (b) is the sum of the A delay (**518 days + 94 days = 612 days**) and the B delay (**1113 days**), less the overlapping period between the A and B delays (**94 days**), a total of **1631 days**.

Applicant delay

The Office has reduced the period of patent term adjustment for a total of 472 days. This reduction includes six periods of applicant delay: (1) a reduction of 89 days under 37 C.F.R. § 1.704(b); (2) a period of 96 days under 37 C.F.R. § 1.704(b); (3) a period of 63 days under 37 C.F.R. § 1.704(b); (4) a period of 194 days under 37 C.F.R. § 1.704(c)(8); (5) a period of 2 days under 37 C.F.R. § 1.704(b); and (6) a period of 24 days under 37 C.F.R. § 1.704(c)(10). Patentees do not dispute delays (1)-(5) indicated above.

Patentees, however, disagree with the application of the 24 day reduction under 37 C.F.R. § 1.704(c)(10) for submission of an amendment under 37 C.F.R. § 1.312. To apply a delay under 37 C.F.R. § 1.704(c), applicants must engage in action or inaction

that constitutes “a failure of the applicant to engage in reasonable efforts to conclude processing or examination of an application.” The amendment under 37 C.F.R. § 1.312 was provided solely because the Office objected to the drawings in the Notice of Allowance. Because this amendment was filed at the request of the Office, its inclusion with the Reply to Notice of Allowance and Payment of Issue Fee does not constitute a failure to engage in reasonable efforts to conclude processing or examination of an application, and thus should not result in a reduction of patent term.

Accordingly, Patentees believe the proper period for reduction of patent term adjustment due to applicant delay is **448 days**.

Total patent term adjustment

Based on the above calculations, the Office delay associated with the present patent is **1631 days** and the applicant delay is **448 days**. Thus, the patent is entitled to a total of 1631 days - 448 days = **1183 days** of patent term adjustment under 37 C.F.R. § 1.703. Patentees request that the patent term adjustment determination be corrected accordingly.

CONCLUSION

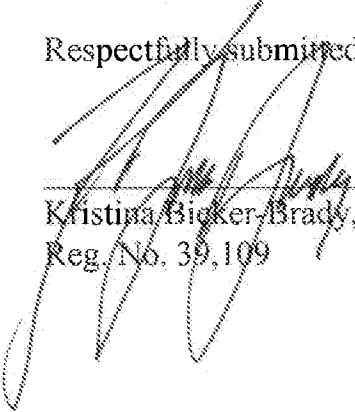
Patentees respectfully request that the Office issue a Certificate of Correction indicating the correct patent term adjustment period of **1183 days**. Transmitted herewith

is \$200.00 in payment of the fee set forth in 37 C.F.R. § 1.18(e). If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date:

November 7, 2009



Kristina Bicker-Brady, Ph.D.
Reg. No. 39,109

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045